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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,483	11/13/2001	Edward Allan Ross	1367-2	5585
7590	03/16/2004		EXAMINER	
Sheldon Palmer c/o Galvin & Palmer 7th Floor 630 Third Avenue New York, NY 10017			DEAK, LESLIE R	
			ART UNIT	PAPER NUMBER
			3762	4
DATE MAILED: 03/16/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/054,483	ROSS, EDWARD ALLAN
	<b>Examiner</b>	Art Unit
	Leslie R. Deak	3762

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### **Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1)  Responsive to communication(s) filed on 13 November 2001.

2a)  This action is FINAL.                            2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4)  Claim(s) 1-33 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5)  Claim(s) \_\_\_\_\_ is/are allowed.  
6)  Claim(s) 1-33 is/are rejected.  
7)  Claim(s) \_\_\_\_\_ is/are objected to.  
8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on 13 November 2001 is/are: a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All    b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_

- 4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_ .

5)  Notice of Informal Patent Application (PTO-152)

6)  Other: \_\_\_\_ .

## DETAILED ACTION

### ***Information Disclosure Statement***

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Generally, the claims are narrative and indefinite and lack antecedent basis for several of the claimed limitations. For example, in claim 1, lines 5 recites the limitation "the near end," and line 15 recites "said inner channel;" both recitations lack antecedent basis. Furthermore, lines 13-14 recite a semipermeable membrane, but it is unclear which portion of the catheter comprises the semipermeable membrane. Finally, the limitations drawn to the manner in which the catheter is designed to be used are not positively claimed. Examiner suggests, for example, in line 8, "inner lumen" --; the catheter is configured to allow a hyperosmotic fluid...--. The

"configured to" language adds a positive functional recitation to a device claim. Such difficulties may also be overcome by means + function claim language.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1, 2, 7-9, 11-16, 22, 23, 28-30, 32, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,980,478 to Gorsuch et al. Gorsuch discloses an intravenous catheter that may comprise a dual lumen 25 with a semipermeable filter element 30 on the distal end of the catheter. The catheter may further comprise a luer connector and a pump and may be comprised in part of polyurethane (see columns 3-4). The lumina may be coaxial or side-by side, and comprise impermeable walls (see incorporated reference US 5,151,082). Gorsuch does not disclose the method claimed by applicant, but the device is capable of performing the method as claimed, so it would be obvious to one of ordinary skill in the art to use the catheter to remove fluid from the plasma with an appropriately sized membrane rather than to remove the plasma entirely, since Gorsuch teaches the removal of metabolic waste, of which excess patient fluid is a component.

6. Claims 4, 5, 10, 25, 26, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,980,478 to Gorsuch et al in view of US 435,231 to Schindler et al. Gorsuch discloses the apparatus as claimed with the exception of the polyamide

material construction and an anchor member. Schindler discloses a semipermeable catheter for in vivo blood purification that discloses a partial construction of polyamide (see column 3). It would have been obvious to one having ordinary skill in the art at the time of invention to use the polyamide, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of design choice. Further, Schindler discloses a sheath 70 with a plurality of holes at the proximal and distal ends to keep the patient vein open and the catheter in place. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to add a sheath or anchor member as disclosed by Schindler to the Gorsuch device in order to retain the catheter in an optimal working position, as taught by Schindler.

***Allowable Subject Matter***

7. Claims 3, 6, 17-21, 24, 27, and 29 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The following is a statement of reasons for the indication of allowable subject matter: The prior art fails to disclose or suggest a dual-lumen catheter with a semipermeable outer wall that uses hyperosmotic fluid to draw excess plasma fluid from the blood and pump the hyperosmotic fluid and the waste water out of the patient. The closest prior art of record, US 5,980,478 to Gorsuch, discloses a dual-lumen catheter with a filter element, but fails to disclose the particular method of fluid removal with the claimed apparatus as claimed by applicant.

***Conclusion***

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

a. US 5,324,518 Orth et al

i. Catheter with semipermeable membrane

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 703-305-0200. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
LRD  
5 March 2004



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SUPERVISORY PATENT EXAMINER  
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